
XI. PREMARKET NOTIFICATION SUMMARY

Pursuant to 513(i)(3)(A) of the Food, Drug and Cosmetic Act, Ceragem Co., Ltd is required to submit with this Pre-market Notification either an "...adequate summary of any information respecting safety and effectiveness or state that information will be made available upon request of any person." Ceragem Co., Ltd. chooses to submit a summary of the safety and effectiveness information. The summary is as follows:

Submitter's Name: CERAGEM Co., Ltd.
177-14, Osaejdabg-ri, Seongger-eup, Cheonan-si,
Chungcheongnam-do, Korea
Contact Person: Kevin Park
Tel: 213.480.7151

Proprietary Name: CERAGEM – RH1 Automatic Thermal Massager

Classification Name: Multi-Function Therapy Table (Class II), 21 CFR 890.5880

Predicate Devices: CERAGEM - C (K040031)
Ceragem Co., Ltd.

Product Description: The CERAGEM – RH1 Automatic Thermal Massager is an electrically powered motorized multi-functional physical therapy table. Its intended use is to provide muscle relaxation therapy by delivering heat and soothing massage. The massage function is delivered by massage rollers mounted on an independent carriage underneath a pad on the table's torso section. The heat function is delivered by two components: 1) heated jade massage rollers mounted together on the moving carriage and 2) heated Epoxy Carbon Panels. In both cases, radiant infrared heat is emitted. Together, the massage action and heated pressure points apply light pressure as well as heat to the user.

Indications for use:

The intended use of the CERAGEM – RH1 Automatic Thermal Massager is to provide the user with muscle relaxation therapy by delivering heat and soothing massage. Additionally, the product provides topical radiant infrared heat for:

- ◇ temporary relief of minor muscle and joint pain, and stiffness
- ◇ the temporary relief of minor joint pain associated with arthritis
- ◇ the temporary increase in local circulation where applied
- ◇ relaxation of muscles

Conclusion:

Based on comparison of the CERAGEM – RH1 Automatic Thermal Massager to the predicate device, we conclude that the CERAGEM – RH1 Automatic Thermal Massager has the same intended use, with similar functional and performance characteristics as the named predicate. Other distinctions do not impact safety or effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ceragem International, Inc.
% Suzan Onel
Kirkpatrick & Lockhart Nicholson Graham LLP
1601 K Street
Washington, D.C. 20006-1600

OCT 31 2006

Re: K062476
Trade Name: CERAGEM RH-1 Automatic Thermal Massager
Regulation Number: 21 CFR 890.5880
Regulation Name: Multi-function Physical Therapy Table
Regulatory Class: Class II
Product Code: JFB
Dated: August 23, 2006
Received: August 24, 2006

Dear Ms. Onel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

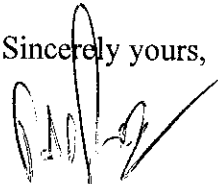
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Ms. Suzan Onel

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', with a long, sweeping horizontal stroke extending to the right.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K062476

Device Name: CERAGEM – RH1 Automatic Thermal Massager

Indications For Use:

The intended use of the CERAGEM – RH1 Automatic Thermal Massager is to provide muscle relaxation therapy by delivering heat and soothing massage. Additionally, the product provides topical radiant infrared heat for:

- temporary relief of minor muscle and joint pain and stiffness
- temporary relief of minor joint pain associated with arthritis
- temporary increase in local circulation where applied
- relaxation of muscles


Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

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